Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
SM-5455-DIV-US (112713-1304)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on October 17, 2005

Signature [signature]

Typed or printed name Heather Foster

Application Number	Filed
09/970,580	October 4, 2001

First Named Inventor: Bilstad

Art Unit	Examiner
1744	Krisanne M. Jastrzab

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [X] attorney or agent of record. Registration number Reg. 46,639
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

[signature]
Signature

Robert W. Connors
Typed or printed name

312-807-4214
Telephone number

October 17, 2005
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Corres. and Mail
BOX AF

Applicants:	Bilstad et al.
Appl. No.:	09/970,580
Conf. No.:	2598
Filed:	October 4, 2001
Title:	METHOD AND APPARATUS FOR MANIPULATING PRE-STERILIZED COMPONENTS IN AN ACTIVE STERILE FIELD
Art Unit:	1744
Examiner:	KRISANNE M. JASTRZAB
Docket No.:	SM-5455-DIV-US (112713-1304)

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE ACCOMPANYING A PRE-APPEAL BRIEF REQUEST FOR REVIEW

Madame:

This request is submitted in response to the Final Office Action dated **May 19, 2005**. This request is filed contemporaneously with a form PTO/SB/33, "Pre-Appeal Brief Request for Review"; a form PTO/SB/31, "Notice of Appeal"; and a Request for Two-Month Extension of Time,

Remarks begin on page 2 of this paper.

REMARKS

This request and remarks are submitted in response to the clear errors maintained in the final Office Action and Advisory Action mailed May 19, 2005 and August 3, 2005, respectively. No amendments and no new matter are introduced by this paper. A check in the amount of $950.00 is submitted herewith to cover the fee for the Notice of Appeal set forth under 37 C.F.R. §41.20(b)(1) and the petition fee for a two-month extension of time set forth under 37 C.F.R. §1.17(a)(2). Applicants submit that no additional claim or petition fees are required in connection with this application. Applicants request that any additional fee or cost, excluding the issue fee, be charged to **Deposit Account No. 02-1818**.

I. STATUS OF CLAIMS

Claims 18 to 33 remain pending and at issue in this application with Claims 1 to 17 and 34 to 65 having been previously canceled without prejudice. By this response, none of the pending claims 18 to 33 are amended and no new claims have been added.

II. CLAIM REJECTIONS

The Office Action erroneously maintains the rejection of claims 18 to 33 under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 3,780,308 (hereinafter "*Nablo*"). Applicants traverse the rejections of claims 18 to 33 as obvious over *Nablo* for at least the following reasons. In particular, claim 18 recites, in relevant part, a method for sterile filling a pre-sterilized container having a filling port with a bulk sterile fluid that includes introducing a filling port of a pre-sterilized container into the sterilizing field and transferring an aliquot of a bulk sterile fluid from a supply container to the pre-sterilized container through the filling port while in the a sterilizing field. In other words, the transfer of the bulk sterile fluid between the supply container and the filling port of the pre-sterilized container is accomplished while at least a portion of both containers are within the same sterilizing field, i.e., an area in which bacteria or other contaminants cannot survive.

Nablo does not, at any level, disclose or even suggest a device in which transfer of the bulk sterile fluid between the supply container and the filling port of the pre-sterilized container is accomplished while at least a portion of both containers are within the same sterilizing field. *Nablo* discloses an aseptic packaging system that includes a central pulser adapted to sequentially excite the sterilizing heads A, B, C positioned serially along the length of a

conveyor 8. The sequentially operating sterilizing heads A, B and C correspond to the package 7, the filler spot 3' and package lid, respectively. *See* col. 6, lines 24 to 32. Thus, when the head A is communicating an excitation field to the package 7, the filler spout 3' is not with the excitation field. Similarly, when the head B is communicating an excitation field to the filler spout 3' during the filling operation (see FIGS. 5a and 5b) the package 7 is not within the excitation field. Thus, because only one of the heads A, B and C is active and communicating an excitation field at any given time, it is impossible for both the package 7 and the filler spout 3' to be within the same excitation field such that the transfer of the bulk sterile fluid between the supply container and the filling port of the pre-sterilized container is accomplished while at least a portion of both containers are within the same sterilizing field as recited claim 18.

In response to these arguments, the Office Action erroneously alleges that the high concentration of ozone in zone 4 is the sterilizing field recited in the claims. This allegation is both logically and factually lacking. For example, while the Office Action acknowledges that the ozone is created as a byproduct when air interacts with the sterilizing field established by excitation energy, the Action simultaneously attempts to assert that the ozone byproduct is the sterilizing field from which it was created. Furthermore, while it is clear that high concentrations of ozone may assist in *maintaining the sterile condition* established by the sterilizing field, it is the sterilizing field *and not the ozone* that initially creates the sterile condition. If, for the sake of argument, ozone were a sterilizing field that, by itself, creates a sterile condition, the air purification and overpressure systems utilized within zone 4 would be completely unnecessary and redundant because any contaminant entering zone 4 would be killed upon contact with the ozone. For all of these reasons, Applicants assert that the high concentration of ozone in zone 4 is not a sterilizing field as alleged.

Applicants further traverse the allegation that a portion of the supply container is not within the same sterilizing field. Claim 18 expressly states that the steps for sterile filling include: (1) establishing a controlled sterilizing field, (2) introducing a filling port [of a pre-sterilized container, see the claim preamble] into the sterilizing field, and (3) transferring an aliquot of a bulk sterile fluid from a supply container to the pre-sterilized container through the filling port while in the sterilizing field. From this, it is clear, that the filling port of the pre-sterilized container is within the sterilizing field and liquid is transferred through the filling port

while in the sterilizing field, thus at least a portion of the supply container must be in the sterilizing field and in contact with the filling port in order to affect transfer of the liquid.

For all of these reasons, Applicants assert that claims 18 to 33 are not rendered obvious by the teachings and disclosure of *Nablo*. Specifically, *Nablo* does not teach each and every element in the recited by the claims. As previously discussed in the Response dated July 19, 2005, Applicants prove that *Nablo* does not teach or even suggest a device in which transfer of the bulk sterile fluid between the supply container and the filling port of the pre-sterilized container is accomplished while at least a portion of both containers are within the same sterilizing field. Rather *Nablo* discloses sterilizing the package 7, moving the package 7 out of the excitation field and *then* filling the package 7 via a sterilized filler spout. The system of *Nablo* risks contamination because both elements are not in the excitation field simultaneously, and the ozone within packaging region 4 does not establish an area in which bacteria or other contaminants cannot survive. Thus, the pending claims are patentable over any variation of modification of *Nablo*

III. CONCLUSION

For the foregoing reasons, Applicants submit that the present application is now in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY: _____

Robert W. Connors
Reg. No. 46,639
P.O. Box 1135
Chicago, Illinois 60690-1135
Telephone: (312) 807-4214

Dated: October 17, 2005